

Efficacy of Vaginal Misoprostol in Second-trimester Abortion

Atima Bharti¹, Seema Kumari²

¹Assistant Professor, Department of Obstetrics and Gynaecology, Rajendra Institute of Medical Science, Ranchi, Jharkhand, India,

²DGO, EX-PG Resident, Department of Obstetrics and Gynaecology, Rajendra Institute of Medical Science, Ranchi, Jharkhand, India

Abstract

Introduction: Abortion is one of the most fundamental health care needs of a woman! Abortion is defined as the termination of pregnancy by any means before the fetus is viable.

Aim: To provide a review on mid-trimester abortion with vaginal misoprostol which is effective, safe, and acceptable with minimal side effects lasting for a transient period.

Materials and Methods: A prospective study was conducted in the Department of Obstetrics and Gynecology. A total of 100 patients were selected from Outpatient Department and labor room having a gestational age of 13-20 weeks. Irrespective of age, marital status and parity these patients seeking for abortion were induced with vaginal misoprostol for labor induction. The results were analyzed.

Results: Maximum number of patients 44% were in the age of 26-30 years. About 80% of women belonged to urban community, and the majority of women 88% were literate while only 12% were illiterate. About 64% belonged to lower and middle socio-economic class while only 2% belonged to rich/high socio-economic class. Exactly 81% patients had 3 or more children, 5% were primigravidae, and 14% had 1 or 2 children. Contraceptive failure temporary and permanent accounted for 9% of women wanting abortion. Women having gestational age of 17-20 weeks, 100% aborted within 24 h and 76% aborted within 24 h in women having gestational age of 13-16 weeks. About 88% of cases with gestational age of 13-20 weeks had complete abortion within 24 h and did not require surgical evacuation. Exactly 12% of patients with gestational age of 13-16 weeks required surgical evacuation for placental bits and membrane. This observation was found statistically significant.

Conclusion: Misoprostol is highly effective drug for second-trimester abortion. It is inexpensive, safe, stable at room temperature, easily available, easy to use with minimum side effects.

Key words: Efficacy, Gestational age, Mid-trimester termination, Misoprostol, Parity

INTRODUCTION

Abortion is one of the most fundamental health care needs of a woman! Abortion is defined as the termination of pregnancy by any means before the fetus is viable. Viability is considered to be reached at 23-24 weeks of gestation. Mid-trimester is a period ranging from 13 to 28 weeks of gestation which again is subdivided into an early period between 13 and 20 weeks

and a late period between 20 and 28 weeks. In our review, we have limited up to 20 weeks gestations taking in consideration the medical termination of pregnancy (MTP) act.

Medical abortion is a safe option for second-trimester abortion in indicated cases. It is a safe alternative to a surgical method. MTP was legalized in the year 1971.¹ In the year 2002 and 2003, there was an amendment to the MTP act which sanctioned Obstetrician and Gynecologist to provide mifepristone and misoprostol in a clinical setting up to 7 weeks of pregnancy.

The efficacy of misoprostol in second-trimester abortions has been reported.^{2,3}

It is found in clinical studies that vaginal route of misoprostol administration is a more effective as it bypasses extensive

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Corresponding Author: Atima Bharti, 21 Ashashree Garden, Near R. K Mission Ashram, Morabadi, Ranchi, Jharkhand, India.

Phone: +91-9431107457. E-mail: dratimabharti@gmail.com

and rapid first pass metabolism. Although effective but cumbersome, as it requires repeated vaginal examination for misoprostol induction which is inconvenient and at times may be unacceptable to the patients. Misoprostol is marketed as an oral preparation used to prevent and treat gastroduodenal damage induced by nonsteroidal anti-inflammatory drug. However, misoprostol is used for a variety of indications in the practice of obstetrics and gynecology, including medical abortion, medical management of miscarriage, induction of labor, cervical ripening before surgical procedures and the treatment of postpartum hemorrhage.⁴

Misoprostol is a synthetic 15-deoxy-16-hydroxy, 16-methyl analog of the naturally occurring prostaglandin (PG). It is an effective abortifacient and uterotonic drug. It is formulated for oral use but is effective by vaginal, buccal and sublingual administration for the purpose of abortion.⁵ It is stable at room temperature, is easily available, inexpensive and has a long half-life.

Demetroulis *et al.*, 2001,⁶ randomized controlled trial has reported a success of 82.5% as compared to surgical treatment with no difference in relation to incidence, duration or severity of bleeding.

With the improvement of ultrasound technology and noninvasive blood tests, the likelihood of detection of major fetal structural abnormalities in mid-pregnancy has increased considerably. On detection of serious anomalies, women are offered the option of termination. In addition, there are still many reasons other than fetal anomalies, why women seek abortion in the mid-trimester. It is an option for women who are poor surgical candidates and also for those who live in areas where surgical termination is not available.

In the Cochrane review 2011, medical abortion in the second-trimester using the combination of mifepristone and misoprostol was found to have the highest efficacy and shortest abortion interval. If mifepristone is not available, misoprostol alone is a reasonable alternative.⁷

The optimal route for administering misoprostol is vaginal. Apart from pain, the side effects are usually mild and self-limiting.⁷

Misoprostol's effects are dose dependent. Although not approved by the US FDA, in 2002, pregnancy was removed from the label as an absolute contraindication.⁸

MATERIALS AND METHODS

Our study was undertaken in the Department of Obstetrics and Gynecology, Rajendra Institute of Medical

Science, Ranchi. Around 100 patients were selected from the outpatient department and labor room having gestational age of 13-20 weeks. Proper counseling was done, and a written informed consent was obtained before starting the treatment regime. Ultrasonography was done, along with detailed history and proper examination of the patient.

Irrespective of age, marital status and parity, these patients were induced with misoprostol introduced in the posterior fornix. Intravenous antibiotics were administered on admission, to all patients after instilling vaginal misoprostol. A value of 400 µg of misoprostol was introduced and repeated at 4 h interval, up to a maximum of 4 doses. Anti-D immunoglobulin (150 µg) was administered to all those with a negative blood group within 72 h of the first dose.

Exclusion Criteria

- Known allergy or previous reaction to PG
- Active renal or hepatic disease
- Scarred uterus
- Cardiac disease
- Severe anemia
- Maternal coagulopathy.

Indication for seeking mid-trimester abortion:

- Unmarried
- Low socio-economic
- Having a small child or two or more children
- Failure of contraception
- Congenital abnormalities of fetus.

After admitting the patients, relevant laboratory investigations were done. Date and time of induction of the first dose of misoprostol were noted. Patients were observed for painful uterine contraction and 400 µg was repeated at 4 h interval. Date and time of abortion were observed. Any additional treatment if given was noted down along with side effect and complications if any.

RESULTS

This prospective study was performed in 100 patients seeking abortion in the second-trimester. Each patient was given 400 µg of misoprostol in the posterior fornix and repeated at 4 h interval.

- a. Maximum numbers of patients 44% were in the age group of 26-30 years.
- b. Patients with an urban background accounted for 80% of the case while 20% belonged to the rural community. As the institute is situated in an urban area, so it is convenient for the women to come.
- c. The majority number of women 64% belonged to

lower and middle socioeconomic class. Only 2% belonged to rich/high socioeconomic class. The reason for this distinct difference is the use of contraceptive measures and resort to the permanent method of sterilization once their family is complete. Among the lower middle class, the situation is different. They are unable to rear more children and due to unawareness, poverty and poor transport diagnosis of pregnancy is late.

- d. The majority of the cases in the study 88% were literate and 12% were illiterate. Maximum number of cases 70% had studied up until XII Std. The high percentage of literacy in the present study could be because of the fact that the majority of the cases were from urban areas where literacy level is higher than in rural areas.
- e. About 81% of patients who came for mid-trimester abortion had three or more children and only 5% were primigravida. Exactly 14% of cases had one or two children. This shows that parity has a close relation with women wanting abortion. Since they had completed their family hence not desirous for another pregnancy (Table 1 and Graph 1).
- f. Among patients seeking mid-trimester abortion, the common indication was low-socioeconomic status and inability to rear another child in 64% of cases. About 18% of patients had conceived soon after delivery in lactation amenorrhea, hence not aware of gestational age. Having a small child was the reason behind seeking for mid-trimester abortion.
- g. Contraceptive failure was the reason for abortion in 7% of patients and tubectomy failure in 2% of cases (Table 2 and Graph 2).
- h. 50 cases were of 13-16 weeks gestation and majority 39% who sought mid-trimester abortion had a gestation of 16 weeks while 50 cases had gestation 17-20 weeks (Table 3 and Graph 3).
- i. Overall success rate in 13-16 weeks and 17-20 weeks with vaginal misoprostol was 100% in this study. Patients with 13-16 weeks gestation aborted within 24 h in 76% of cases and in 17-20 weeks groups 100% aborted within 24 h (Tables 4-6 and Graphs 4-6).

DISCUSSION

There is a wide variation in doses used at different stage of gestation, means that it is important to have an accurate diagnosis before commencing treatment. For this reason, many health services will make misoprostol available only at a level where both trained staff and facilities for diagnosis are available.

In the largest published series ($n = 1002$, gestation age 13-21 weeks), 97% of women aborted within 24 h, with

mean induction time of 5.9 h for multiparous women and 6.6 h for nulliparous women.⁹

This regime is on the basis of recommendation by the World Health Organization and Royal College of Obstetricians and Gynecologists based on trials that included women predominantly at 20 weeks gestation or less.

- j. 88% of patients had complete abortion within 24 h (Table 6) and did not require surgical evacuation. These patients had gestation of 17-20 weeks. 12% of patients with 13-16 weeks of gestation required surgical

Table 1: Distribution of cases according to parity

Parity	Number of cases
0	5
1	4
2	10
3	32
4	23
5	16
>5	10
Total	100

Table 2: Distribution according to reasons seeking for abortion

Reason for abortion	Number of cases
Unmarried	7
Socio-economic	64
Having small children	18
Contraceptive failure	
Temporary method	7
Permanent method	2
Congenital anomalies	2
Total	100

Table 3: Distribution of cases according to gestational age

Gestational age (weeks)	Number of cases
13-16	50
17-20	50
Total	100

Table 4: Distribution according to induction-abortion interval in 13-16 weeks gestation by vaginal misoprostol

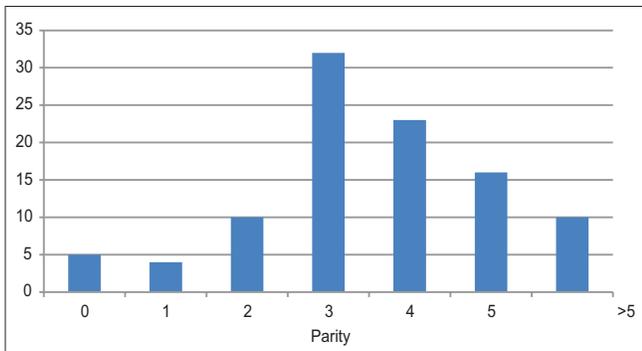
Induction-abortion interval in (h)	Number of cases	Percentage of cases
00-12	2	4
12-24	36	72
24-36	8	16
36-48	4	8
Total	50	100

Table 5: Distribution according to induction-abortion interval in (17-20 weeks) gestation

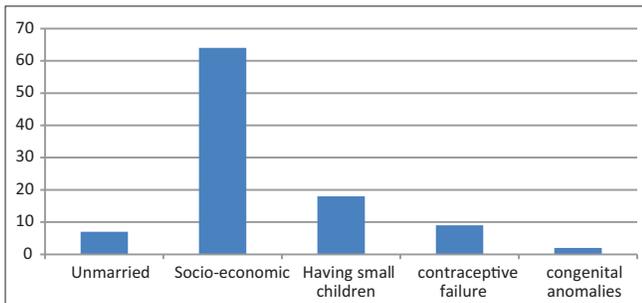
Induction-abortion interval in (h)	Number of cases	Percentage of cases
00-12	11	22
12-24	39	78
Total	50	100

Table 6: Comparison of efficacy of misoprostol in 13-16 weeks gestation and 17-20 weeks in first 24 h

Gestational age (weeks)	Number of cases	Percentage of cases
13-16	38	76
17-20	50	100
Total	88	88



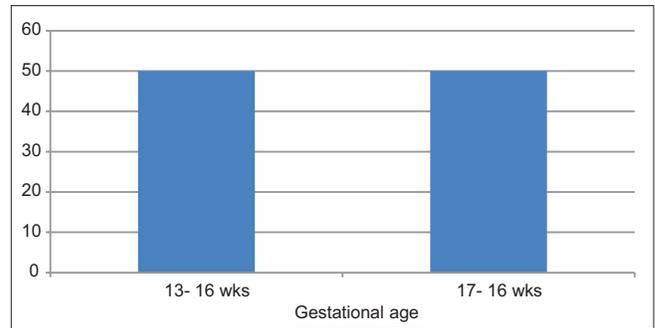
Graph 1: Distribution of cases according to parity



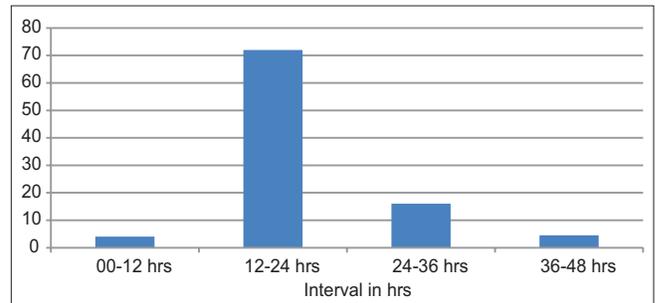
Graph 2: Distribution according to reasons seeking for abortion

evacuation of placental bits and membranes. This observation was found to be statistically significant. Lo *et al.*, noted the pregnancies with <17 weeks gestation had a higher rate of incomplete abortion and operational procedure as compared to more than 20 weeks.¹⁰

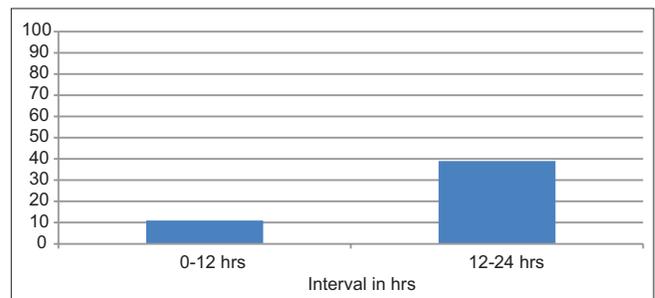
Few studies follow the natural course of placental expulsion without intervention for placental delivery. In women receiving misoprostol alone for labor induction abortion, half of women deliver the placenta within an hour, and there was no increase in bleeding when women were



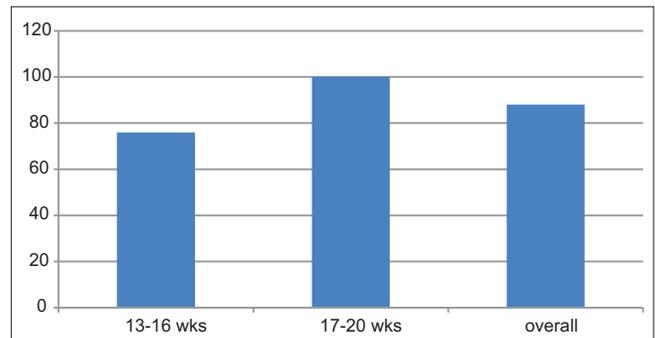
Graph 3: Cases according to gestational age



Graph 4: Induction-abortion interval in 13-16 weeks gestation



Graph 5: Induction-abortion interval in 17-20 weeks gestation



Graph 6: Misoprostol efficacy in first 24 h

observed past 2 h. This study also showed that routine misoprostol administration after fetal expulsion did not decrease the time to placental delivery.¹¹

Dickinson and Evans randomized women to receive intramuscular oxytocin, oral misoprostol or no medication

after fetal delivery. After oxytocin 90% of women expelled the placenta within an hour, compared to 71% and 69% after misoprostol or no medication respectively.¹²

- k. Side effects associated with misoprostol was nausea and vomiting 2%, fever 6%, diarrhea 2% and bleeding 2%. However, these side effects were mild and self-limiting. There was no major complication in this study. Fever is at times confused with infection but resolves within several hours of stopping misoprostol. The incidence of side effects is also lower for vaginal use except for transient fever.¹³

While isolated case reports and retrospective review documents uterine rupture during second-trimester induction with misoprostol, the magnitude of the risk is not known.¹⁴ Second-trimester abortion constitutes 10-15% of all induced abortion worldwide but are responsible for two-third of major abortion-related complications.¹⁵

Because of potential for heavy vaginal bleeding and serious complications, it is advisable that second-trimester abortion takes place in a healthcare facility where blood transfusion facility and emergency surgery including laparotomy are available. When fetal anomaly causes a woman to seek second-trimester abortion, oral administration of misoprostol appears to be the least effective method for terminating the pregnancy and vaginal misoprostol is more acceptable to women.¹⁶

Pregnancies with fetal demise may be treated similarly but the doses necessary to cause fetal expulsion is lower and induction process is typically shorter.¹⁷⁻²⁰

Majority of second-trimester abortion performed in the United States are performed surgically by dilatation and evacuation.²¹

Whereas labor-induction abortion represents approximately 2% of second-trimester abortion in the United States,²² more than 80% of abortions throughout the second-trimester in Sweden and other Nordic countries are inductions.²³

CONCLUSION

The incidence of second-trimester abortion has significantly reduced off-late, thanks to the PNDA act. Yet, when the condition is not favorable, either for the fetus or mother, the benefits of pregnancy termination outweighs the risk of continuation. This process, rightly known as mini-labor, is not only painful physically but also has a psychological impact. Second-trimester abortion carries a higher financial cost to individuals, medical institution and society. It

remains a necessary procedure despite higher risk and cost compared to first-trimester procedure, due to advances in antenatal diagnosis, decreased access to timely early abortion care and medical complications of pregnancy in the second-trimester.

The majority of women have no long-term psychological sequelae, but short time grief may be considerable, particularly for those choosing to terminate a desired pregnancy. Overall misoprostol appears to be more effective than $\text{PGF}_2\alpha$, PGE_2 , high dose oxytocin and ethacryndine lactate when adequate doses are used. Both PGE_2 and $\text{PGF}_2\alpha$ analogs are expensive and require refrigeration, in contrast to misoprostol, which is inexpensive and stable at room temperature.

Misoprostol used alone or in combination with other uterotonic agents have supplanted most other methods, because of high efficacy, cost-effective, wide availability and easy to use.

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